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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,513	07/05/2001	Yi Hu	LEX-0200-USA	9922

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EXAMINER

LI, RUIXIANG

ART UNIT PAPER NUMBER

1646

DATE MAILED: 07/30/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/899,513

Applicant(s)

HU ET AL.

Examiner

Ruixiang Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 5-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicants' election without traverse of Group III (Claim 5), drawn to an expression vector comprising a nucleotide sequence that encodes SEQ ID NO: 2 and hybridizes to SEQ ID NO: 1, in Paper No. 8 filed on 06/27/2002 is acknowledged.
2. Applicants' claim amendment of 6/27/2002 in Paper No. 8 is acknowledged. Claims 1-4 have been canceled. Claim 5 has been amended. Claims 6 and 7 have been added. Claims 5-7 are pending and under consideration.
3. Applicants' request to amend inventorship has been approved. In view of the papers filed on June 27, 2002, the inventorship in this nonprovisional application has been changed by the deletion of Yi Hu, C. Alexander Turner, Jr., and Boris Nepomnichy.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of the file jacket and PTO PALM data to reflect the inventorship as corrected.

### ***Priority***

4. Acknowledgment is made of a claim for domestic priority under 35 U.S.C. 119(e) to a provisional application, 60/217,600, filed on 07/11/2000.

### ***Rejections—35 USC § 101***

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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6. Claims 5-7 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

Claims 5-7 are drawn to an expression vector comprising a nucleotide sequence that encodes SEQ ID NO: 2 and hybridizes to SEQ ID NO: 1, an expression vector comprising the nucleotide sequence of SEQ ID NO: 1, and a host cell comprising the expression vector. The claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. A specific and substantial utility is one that is particular to the subject matter claimed and that identifies a "real world" context of use for the claimed invention which does not require further research.

The instant disclosure asserts that the deduced amino acid sequence set forth in SEQ ID NO: 2 shares sequence similarity with mammalian membrane proteins (page 1, lines 8-11; page 2, 1<sup>st</sup> and 2<sup>nd</sup> paragraphs). Nonetheless, the disclosure fails to disclose the degree of homology and, more importantly, fails to provide any information or evidence on the biological functions or activities of the claimed molecules. In view of the diversity of structure and functions of the proteins, prediction of function using comparative sequence analysis may lead to the creation and propagation of assignment errors if not performed appropriately (See, Peer Bork and Eugene V. Koonin, Predicting functions from protein sequences--where are the bottlenecks? *Nature Genetics* 18:313-318,1998). There are putative seven transmembrane molecules, which do not appear to be coupled to a G protein (Ji et al.

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G-protein-coupled receptors, *J. Biol. Chem.*, 273:17299-17302, 1998). In certain cases, a change of two-amino acid residues in a protein results in switching the binding of the protein from one receptor to another (Yan et al, Two-amino acid molecular switch in an epithelial morphogen that regulates binding to two distinct receptors. *Science*, 290:523-527, 2000). Thus, all the asserted utilities in the disclosure based upon the protein homology are not specific and substantial, as exemplified below.

The instant disclosure asserts that the claimed nucleic acid sequences are useful for identification of coding sequence and mapping a unique gene to a particular chromosome, as well as identification of the actual biologically relevant exon splice junctions (page 3, 2<sup>nd</sup> paragraph). The disclosure also asserts that the nucleotide sequences can be used to regulate gene expression (page 2, 3<sup>rd</sup> paragraph; page 9, 2<sup>nd</sup> paragraph) or can be used as hybridization probes for screening libraries (page 6, 2<sup>nd</sup> paragraph; page 11, 3<sup>rd</sup> paragraph). The disclosure additionally asserts the use of the claimed protein in generation of antibodies (page 19, last paragraph). However, such uses are all considered research uses only designed to identify a particular function of the claimed molecules and are not a substantial utility. See, e.g., *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966) wherein a research utility was not considered a "substantial utility." Moreover, such uses are not specific to the instant molecule but applicable to any nucleic acid molecules or proteins.

The instant disclosure further asserts that the claimed nucleic acid molecules, proteins, fusion proteins, and antibodies “can be useful” for the detection of mutant proteins for the diagnosis of disease (page 15, 3<sup>rd</sup> paragraph), or for screening agonists, antagonist, and drugs (page 3, 3<sup>rd</sup> paragraph; page 15, 3<sup>rd</sup> paragraph). The instant disclosure also asserts that the molecules of the present invention can be used as therapeutics (page 16, 2<sup>nd</sup> paragraph) to directly treat diseases or disorders (page 16, 2<sup>nd</sup> paragraph). These asserted utilities are not specific and substantial because they do not identify or reasonably confirm a “real world” context of use. The specification fails to disclose the biological functions of the claimed molecules and any diseases that are associated with or can be treated with the claimed molecules. Clearly, further research would be required to identify a disease that is associated with the claimed molecules or a disease that can be treated with the claimed molecules. See *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966), noting that “a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.”

The invention also lacks a well-established utility. A well-established utility is a specific, substantial, and creditable utility that is well known, immediately apparent, or implied by the specification’s disclosure of the properties of a material. The assertion that the human protein encoded by the claimed nucleic acid molecules has the sequence similarity with mammalian membrane proteins does not endow the claimed molecules with a specific and substantial utility. No art of record discloses or

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suggests any property or activity for the claimed molecules such that another non-asserted utility would be well-established for the claimed invention.

7. Claims 5-7 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

***Claim Rejections—35 USC § 112, 2<sup>nd</sup> paragraph***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is indefinite because it recites “under stringent conditions”, but without giving the specific conditions in the claim. Neither the specification nor the relevant literature provides an unambiguous definition for the term “stringent conditions”.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282.

The examiner can normally be reached on Monday—Friday, 8:30 am—5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li  
Examiner  
July 20, 2002

  
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